REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herewith, which place the application into condition for allowance.

The Examiner is thanked for confirming that the outstanding Office Action is non-final, even though the Office Action Summary indicates otherwise.

Claims 1, 3-5, 8, 10-15 and 17-32 are pending.

Claims 1, 3, 5, 8, 10-15 and 17-32 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 95/24172 in combination with WO 89/07959; claim 4 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Wick et al., U.S. Patent No. 5,679,373; and claim 32 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Place et al., U.S. Patent No. 5,242,391. These rejections will be addressed collectively and are respectfully traversed. The cited documents, alone or in combination, do not teach or suggest the present invention.

The present invention is directed to, *inter alia* a transdermal system consisting of: a) a cover layer, b) an active-ingredient containing polymer layer, c) optionally active-ingredient-containing adhesive layers, and d) a protective layer, wherein the active-ingredient-containing polymer layer comprises water-soluble polymers and the active ingredients are present in the polymer layer in the form of (an) active ingredient solution(s) or dispersion(s) which are not miscible with water.

Applicants' invention addresses, *inter alia*, a problem of providing an inexpensive matrix transdermal system that can be a manufactured on standard machines and that meets the requirements of the body's time dependent need for active ingredients.

To resolve this problem, Applicants have invented a transdermal system that can enable active ingredients to be made available to the human or animal body in a variable manner. For example, the system according to the invention has the advantage of a hydrophilic polymer layer comprising active ingredients in a hydrophobic solvent and/or of a perforation in the drug layer.

WO 95/24172 ("the '172 patent") is clearly distinguishable from the instant claims. In contrast to the present invention, the '172 patent do not enable, disclose, suggest or even motivate a skilled artisan to anchor ingredients in a hydrophobic solvent or provide perforation in the drug layer. The Office Action actually concedes that the "WO 95/24172 does no teach the active ingredient in a hydrophobic solvent or perforation in the drug layer." (Office Action at page 3).

It is respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In the present situation, the '172 patent, alone or in combination with the secondary references, fail to provide the necessary incentive or motivation to modify the reference teachings in order to arrive at the present invention. There is no suggestion or motivation in any

of the references that would lead a skilled artisan to practice the instantly claimed invention, especially an active ingredient in a hydrophobic solvent or of perforations in the drug layer. The '172 patent does not contemplate such a method. Notably, the '172 patent is directed to a system that is compatible with volatile or heat sensitive drugs, enhancers or other components that cannot be subjected to drying and not to the body's time dependent need for active ingredients. Accordingly, the '172 patent, either individually or in any combination, neither teaches nor suggests the present invention.

None of WO 89/07959, U.S. Patent No. 5,679,373, and U.S. Patent No. 5,242,391 remedy the deficiencies inherent in the '172 patent and it is impermissible to pick and choose portions of disparate references in order to formulate an obviousness rejection. None of these references provide a skilled artisan with any reason to modify the '172 patent Indeed, none of the secondary references enable, disclose, suggest or motivate one skilled in the art to the instant method.

WO 89/07959 ("the '959 patent) relates to an occlusive body patch for transdermal administration of an active agent, the use of a microporous polymer in the active layer and that nitroglycerine may be substituted for nicotine. Applicants respectfully submit that the '959 patent does not address the body's time dependent need for active ingredients and provides no expectation of success for the instantly claimed invention. Applicants respectfully emphasize that the only expectation of success is found in Applicants ' specification and nowhere in the '172 patent or the '959 patent.

Further, the '959 patent relates to a microporous membrane which is simply used to define a cavity between a physiologically active substance in liquid form. In contrast, the transdermal system of the instant invention does not contain such a microporous membrane; instead the polymer layer of the instantly claimed transdermal system is perforated. More

specifically the perforations allow for the direct contact between the adhesive layer above the polymer layer and the cover layer and adhesive layer below the polymer layer. Therefore the disclosure of a microporous membrane whose function is to define a cavity of a physiologically active substance in liquid form would not motivate one of ordinary skill in the art to incorporate the perforations as instantly claimed.

In addition, U.S. Patent No. 5,679,373 relates to the controlled release of an active agent to the skin by melt-blending an active agent matrix polymer and U.S. Patent No. 5,242,391 relates to the treatment of erectile dysfunction.

None of the cited references suggests or motivates a skilled artisan to a use a transdermal system of the instant invention including an active ingredient in a hydrophobic solvent or of perforations in the drug layer. Indeed, none of the references enable, disclose, suggest or motivate one skilled in the art to the instant method.

Consequently, WO 95/24172, WO 89/07959, U.S. Patent No. 5,679,373, and U.S. Patent No. 5,242,391, either individually or in any combination, fail to teach or suggest the present invention; and, reconsideration and withdrawal of the Section 103(a) rejections are believed to be in order and such action is respectfully requested.

As this paper is being submitted within the three-month term for reply set by the July 25, 2002 Office Action, no fee is believed to be due. In the event, however, a fee is required for the consideration of this paper, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment, to Deposit Account 50-0320.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of

a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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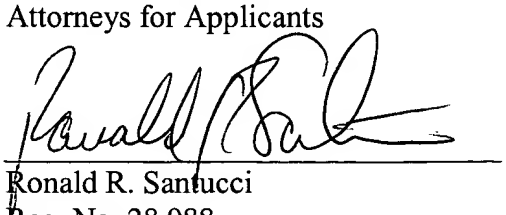
By: 

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